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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,752	08/17/2006	Marco E. Bianchi	2507-1082	7984

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EXAMINER	
SKELDING, ZACHARY S	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
02/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,752	BIANCHI, MARCO E.	
	Examiner	Art Unit	
	ZACHARY SKELDING	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *12-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Your examiner has changed. Please address all future correspondence to Zachary Skelding, Art Unit 1644.

2. Applicant's amendment and remarks filed November 28, 2008 are acknowledged.

   Claims 12-19 are pending.

3. In response to the restriction requirement put forth September 30, 2008, applicant elected the invention of Group I, drawn to a therapeutic agent or inhibitor that binds HMG box, wherein the agent or inhibitor comprises an antibody or antibody fragment, with traverse.

   Applicant traverses on the grounds that: "the technical feature linking Groups I-III appears to be that they all require the technical of an HMG box binding molecule/inhibitor. However, WO 02/074337 neither discloses nor suggests that for which it is offered, namely, use of such compound for treating vascular diseases. Accordingly, applicants respectfully submit that WO 02/074337 fails to satisfy the art-based requirement of PCT Rules 13.1 and 13.2."

   Applicant's argument is not found convincing because applicant has not convincingly argued that the therapeutic inhibitory agents disclosed in WO 02/074337 somehow differ from the claimed agents in a way that would make them unable to perform the claimed intended use: "treatment of vascular diseases related to smooth muscle and endothelial proliferation."

   However, upon reconsideration the previous restriction requirement is hereby VACATED.

   New restriction and election of species requirements are put forth below.

Restriction Requirement

4. Restriction is required under 35 U.S.C. 121 and 372.

   This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

   In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

   Group I, claim(s) 12-15, drawn to methods for treating vascular diseases with HMG box binding molecules chosen from antibodies or antibody fragments, inhibitors, 4 way DNA, and molecules having sequence homology with HMG box and being able to bind a functional HMG box binding domain of the receptor.

Group II, claim(s) 16-19, drawn to drawn to HMG box binding molecules chosen from antibodies or antibody fragments, inhibitors, 4 way DNA, and molecules having sequence homology with HMG box and being able to bind a functional HMG box binding domain of the receptor.

5. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: WO 02/074337 teaches therapeutic inhibitory agents comprising HMG box-binding molecules, including antibodies and four-way DNA, as well as molecules having sequence homology with HMG box (of record, see abstract and page 24 in particular).

Election of species requirement

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A. HMG box binding antibodies or antibody fragments;

B. HMG box binding 4 way DNA; and

C. HMG box binding molecules having sequence homology with HMG box and being able to bind a functional HMG box binding domain of the receptor.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 12-17 and 19.

Chemical compounds A-C above are not regarded as being of similar nature because all of the alternatives do not share a common property or activity. In particular, there is no unifying structural element share by the alternatives. Furthermore the alternatives do not

belong to a recognized class of chemical compounds. For example, the art recognizes that antibodies have far greater serum stability and bioavailability than "four way DNA." Thus, there is a lack of expectation in the art that species A and B will behave in the same way in the context of the claimed invention. See MPEP § 1850.

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A. "A method for treating vascular diseases related to endothelial and smooth muscle cells proliferation ***wherein the vascular disease is due to atherosclerosis***"; and

B. "A method for treating vascular diseases related to endothelial and smooth muscle cells proliferation ***wherein the vascular disease is due to restenosis after blood vessels damage***, including those events that occur after coronary and/or carotid angioplasty, with or without stent positioning, angiographic surgery, and surgery using catheters"

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 12-15.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Atherosclerosis is arterial narrowing due to myriad factors, e.g., buildup of plaque in the arteries.

In contrast, restenosis literally means recurrence of stenosis. In the case of arterial restenosis it is understood in the art to refer a recurrence of arterial narrowing after some treatment that ameliorated the initial stenosis, for example angioplasty. This is reflected in the language of

claim 14. Thus a patient at risk of developing restenosis is a patient who has, by definition, previously had their initial stenosis decreased to some extent by treatment.

Furthermore, "restenosis" encompasses in its breadth any recurrent narrowing of a bodily canal or passage, including, e.g., a narrowing of an intestinal segment or a narrowing of the spinal canal.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZACHARY SKELDING whose telephone number is (571)272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachary Skelding/
Examiner, Art Unit 1644
February 17, 2009